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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,452	06/10/2001	Kazuo Sugamura	2001-0572A	4276

513 7590 03/02/2007

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WASHINGTON, DC 20006-1021

EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/831,452	SUGAMURA ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2, 3 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

2. Prosecution on the merits of this application is reopened on claims 1-3 and 5 considered unpatentable for the reasons indicated below:

Response to Amendment

3. Applicant's arguments filed 8/22/06, with respect to the rejection(s) of claim(s) 2 and 3 under 35 USC § 102 and claim 5 under 35 USC § 102 have been fully considered. The rejections have been recast to better address Applicant's arguments. It is noted that the previous examiner did not address claim 1 in the final rejection, this claim is also addressed below. The rejections below can be considered as new grounds of rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu *et al* (1997, *Genome Res.* 7(4): 353-358) in view of Hutchinson et al (Nucleic Acids Research, 1992, Vol. 20, No.13, pages 345-3462) and further in view of Solovyev et al (Nucleic Acids Research, 1994, Vol. 22, No.24, pages 5156-5163) and Eberhard Passarge (Color Atlas of Genetics, Georg Thieme Verlag Stuttgart, New York, Thieme Medical publishers, Inc. New York, 1995).

Yu *et al.* teach a polynucleotide that is 100% identical to SEQ ID NO: 2 of the current application over a span of 1356 base pairs (see GenBank Accession No. AF052135 (submitted March 5, 1998) and attached alignment-spanning bp 1-1356 of SEQ ID NO: 2). The polynucleotide was contained in a vector. The polynucleotide sequence of Yu *et al.* contains the polynucleotide of SEQ ID NO:2, which encodes the

polypeptide of SEQ ID NO:1. Yu *et al.* does not disclose the polypeptide of SEQ ID NO:2, nor does it disclose which specific fragment of the polynucleotide encodes the polypeptide. Yu (AF052135) does not specifically disclose the start or stop coding regions for the protein but it is apparent from the sequence, based on the teaching in the art (some of which are given below) that Yu (AF052135) contains three candidates for the start codons (117-119; 127-129; 133-135) and one stop codon (1481-1483). Therefore, one of skill in the can ascertain that since there are three start sites and one stop codon then three polypeptides can be translated using the polynucleotide of SEQ ID NO:2. Yu *et al.* does not specifically point out the start and stop codons or method of their use in predicting structure but the level of skill was high in the Molecular Biology arts at the time of filing instant application that this type of analysis was routine, for example:

Hutchinson discloses the state of the art in molecular Biology, where as far back as 1992 computer programs were available that identified coding sequences in long stretches of DNA and predicted translation product of these DNA sequences into their amino acid residues. These sequences were translated to identify and purify new proteins as well as provide databases for searching homologous proteins.

Solovyev discloses the state of the art in molecular Biology, where as far back as 1994 computer programs were available that identified coding sequences in long stretches of DNA and translation of these DNA sequences into their amino acid residues. These sequences were translated to identify and purify new proteins as well

as provide databases for searching homologous proteins. Solovyev specifically teaches identification of translation initiating and terminating sites.

Eberhard Passarge discloses that significance of codon usage as it applies to its encoded polypeptides was well known in the art at the time of filing instant application.

The sequence alignments of AF052135 are given below.

ALIGNMENTS

Protein alignment to DNA

```
RESULT 1
AF052135
LOCUS       AF052135                1462 bp    mRNA    linear   PRI
05-AUG-1998
DEFINITION  Homo sapiens clone 23625 mRNA sequence.
ACCESSION   AF052135
VERSION     AF052135.1  GI:3360444
KEYWORDS    FLI_CDNA.
SOURCE      Homo sapiens (human)
  ORGANISM  Homo sapiens
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
REFERENCE   1  (bases 1 to 1462)
  AUTHORS   Andersson,B., Wentland,M.A., Ricafrente,J.Y., Liu,W. and
Gibbs,R.A.
  TITLE     A 'double adaptor' method for improved shotgun library
construction
  JOURNAL   Anal. Biochem. 236 (1), 107-113 (1996)
  MEDLINE   96207227
   PUBMED   8619474
REFERENCE   2  (bases 1 to 1462)
  AUTHORS   Yu,W., Andersson,B., Worley,K.C., Muzny,D.M., Ding,Y., Liu,W.,
            Ricafrente,J.Y., Wentland,M.A., Lennon,G. and Gibbs,R.A.
  TITLE     Large-scale concatenation cDNA sequencing
  JOURNAL   Genome Res. 7 (4), 353-358 (1997)
  MEDLINE   97264341
   PUBMED   9110174
REFERENCE   3  (bases 1 to 1462)
  AUTHORS   Yu,W., Sarginson,J. and Gibbs,R.A.
  TITLE     Direct Submission
  JOURNAL   Submitted (05-MAR-1998) Molecular and Human Genetics, Baylor
            College of Medicine, One Baylor Plaza S930, Houston, TX 77030, USA
FEATURES             Location/Qualifiers
```

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                     /organism="Homo sapiens"
                     /mol_type="mRNA"
                     /db_xref="taxon:9606"
                     /clone="I.M.A.G.E. Consortium clone ID 23625"
                     /sex="female"
                     /tissue_type="brain"
                     /clone_lib="1NIB"
                     /dev_stage="infant"
ORIGIN

Alignment Scores:
Pred. No.:              3.57e-171      Length:          1462
Score:                  2208.00        Matches:         424
Percent Similarity:     100.00%        Conservative:    0
Best Local Similarity:  100.00%        Mismatches:      0
Query Match:            100.00%        Indels:          0
DB:                     9              Gaps:            0

US-09-831-452-1 (1-424) x AF052135 (1-1462)

Qy          1 MetSerAspHisGlyAspValSerLeuProProGluAspArgValArgAlaLeuSerGln 20
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        117 ATGTCTGACCATGGAGATGTGAGCCTCCCGCCCGAAGACCGGGTGAGGGCTCTCTCCCAG 176

Qy         21 LeuGlySerAlaValGluValAsnGluAspIleProProArgArgTyrPheArgSerGly 40
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        177 CTGGGTAGTGCGGTAGAGGTGAATGAAGACATTCCACCCCGTCGGTACTTCCGCTCTGGA 236

Qy         41 ValGluIleIleArgMetAlaSerIleTyrSerGluGluGlyAsnIleGluHisAlaPhe 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        237 GTTGAGATTATCCGAATGGCATCCATTTACTCTGAGGAAGGCAACATTGAACATGCCTTC 296

Qy         61 IleLeuTyrAsnLysTyrIleThrLeuPheIleGluLysLeuProLysHisArgAspTyr 80
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        297 ATCCTCTATAACAAGTATATCACGCTCTTTATTGAGAAACTACCAAAACATCGAGATTAC 356

Qy         81 LysSerAlaValIleProGluLysLysAspThrValLysLysLeuLysGluIleAlaPhe 100
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        357 AAATCTGCTGTCATTCCTGAAAAGAAAGACACAGTAAAGAAATTAAAGGAGATTGCATTT 416

Qy        101 ProLysAlaGluGluLeuLysAlaGluLeuLeuLysArgTyrThrLysGluTyrThrGlu 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        417 CCCAAAGCAGAAGAGCTGAAGGCAGAGCTGTTAAAACGATATACCAAAGAATATACAGAA 476

Qy        121 TyrAsnGluGluLysLysLysGluAlaGluGluLeuAlaArgAsnMetAlaIleGlnGln 140
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        477 TATAATGAAGAAAAGAAGAAGGAAGCAGAGGAATTGGCCCGGAACATGGCCATCCAGCAA 536

Qy        141 GluLeuGluLysGluLysGlnArgValAlaGlnGlnLysGlnGlnGlnLeuGluGlnGlu 160
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        537 GAGCTGGAAAAGGAAAAACAGAGGGTAGCACAACAGAAGCAGCAGCAATTGGAACAGGAA 596

Qy        161 GlnPheHisAlaPheGluGluMetIleArgAsnGlnGluLeuGluLysGluArgLeuLys 180
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                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        597 CAGTTCCATGCCTTCGAGGAGATGATCCGGAACCAGGAGCTAGAAAAAGAGCGACTGAAA 656

Qy        181 IleValGlnGluPheGlyLysValAspProGlyLeuGlyGlyProLeuValProAspLeu 200
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        657 ATTGTACAGGAGTTTGGGAAGGTAGACCCTGGCCTAGGTGGCCCGCTAGTGCCTGACTTG 716

Qy        201 GluLysProSerLeuAspValPheProThrLeuThrValSerSerIleGlnProSerAsp 220
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        717 GAGAAGCCCTCCTTAGATGTGTTCCCCACCTTAACAGTCTCATCCATACAGCCTTCAGAC 776

Qy        221 CysHisThrThrValArgProAlaLysProProValValAspArgSerLeuLysProGly 240
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        777 TGTCACACAACTGTAAGGCCAGCTAAGCCACCTGTGGTGGACAGGTCCTTGAAACCTGGA 836

Qy        241 AlaLeuSerAsnSerGluSerIleProThrIleAspGlyLeuArgHisValValValPro 260
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        837 GCACTGAGCAACTCAGAAAGTATTCCCACAATCGATGGATTGCGCCATGTGGTGGTGCCT 896

Qy        261 GlyArgLeuCysProGlnPheLeuGlnLeuAlaSerAlaAsnThrAlaArgGlyValGlu 280
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        897 GGGCGGCTGTGCCCACAGTTTCTCCAGTTAGCCAGTGCCAACACTGCCCGGGGAGTGGAG 956

Qy        281 ThrCysGlyIleLeuCysGlyLysLeuMetArgAsnGluPheThrIleThrHisValLeu 300
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        957 ACATGTGGAATTCTCTGTGGAAAACTGATGAGGAATGAATTTACCATTACCCATGTTCTC
1016

Qy        301 IleProLysGlnSerAlaGlySerAspTyrCysAsnThrGluAsnGluGluGluLeuPhe 320
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1017 ATCCCCAAGCAAAGTGCTGGGTCTGATTACTGCAACACAGAGAACGAAGAAGAACTTTTC
1076

Qy        321 LeuIleGlnAspGlnGlnGlyLeuIleThrLeuGlyTrpIleHisThrHisProThrGln 340
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1077 CTCATACAGGATCAGCAGGGCCTCATCACACTGGGCTGGATTCATACTCACCCCACACAG
1136

Qy        341 ThrAlaPheLeuSerSerValAspLeuHisThrHisCysSerTyrGlnMetMetLeuPro 360
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1137 ACCGCGTTTCTCTCCAGTGTCGACCTACACACTCACTGCTCTTACCAGATGATGTTGCCA
1196

Qy        361 GluSerValAlaIleValCysSerProLysPheGlnGluThrGlyPhePheLysLeuThr 380
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1197 GAGTCAGTAGCCATTGTTTGCTCCCCCAAGTTCCAGGAAACTGGATTCTTTAAACTAACT
1256

Qy        381 AspHisGlyLeuGluGluIleSerSerCysArgGlnLysGlyPheHisProHisSerLys 400
                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1257 GACCATGGACTAGAGGAGATTTCTTCCTGTCGCCAGAAAGGATTTCATCCACACAGCAAG
1316

Qy        401 AspProProLeuPheCysSerCysSerHisValThrValValAspArgAlaValThrIle 420
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                ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1317 GATCCACCTCTGTTCTGTAGCTGCAGCCACGTGACTGTTGTGGACAGAGCAGTGACCATC
1376

Qy        421 ThrAspLeuArg 424
                ||||||||||||
Db       1377 ACAGACCTTCGA 1388
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Alignment DNA to DNA

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RESULT 5
AF052135
LOCUS       AF052135                1462 bp    mRNA    linear   PRI 05-AUG-
1998
DEFINITION  Homo sapiens clone 23625 mRNA sequence.
ACCESSION   AF052135
VERSION     AF052135.1  GI:3360444
KEYWORDS    FLI_CDNA.
SOURCE      Homo sapiens (human)
  ORGANISM  Homo sapiens
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
REFERENCE   1  (bases 1 to 1462)
  AUTHORS   Andersson,B., Wentland,M.A., Ricafrente,J.Y., Liu,W. and
Gibbs,R.A.
  TITLE     A 'double adaptor' method for improved shotgun library
construction
  JOURNAL   Anal. Biochem. 236 (1), 107-113 (1996)
  MEDLINE   96207227
   PUBMED   8619474
REFERENCE   2  (bases 1 to 1462)
  AUTHORS   Yu,W., Andersson,B., Worley,K.C., Muzny,D.M., Ding,Y., Liu,W.,
            Ricafrente,J.Y., Wentland,M.A., Lennon,G. and Gibbs,R.A.
  TITLE     Large-scale concatenation cDNA sequencing
  JOURNAL   Genome Res. 7 (4), 353-358 (1997)
  MEDLINE   97264341
   PUBMED   9110174
REFERENCE   3  (bases 1 to 1462)
  AUTHORS   Yu,W., Sarginson,J. and Gibbs,R.A.
  TITLE     Direct Submission
  JOURNAL   Submitted (05-MAR-1998) Molecular and Human Genetics, Baylor
            College of Medicine, One Baylor Plaza S930, Houston, TX 77030, USA
FEATURES             Location/Qualifiers
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                     /mol_type="mRNA"
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                     /clone="I.M.A.G.E. Consortium clone ID 23625"
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                     /sex="female"
                     /tissue_type="brain"
                     /clone_lib="1NIB"
                     /dev_stage="infant"
ORIGIN

  Query Match             71.0%;  Score 1356;  DB 9;  Length 1462;
  Best Local Similarity   100.0%;  Pred. No. 0;
  Matches 1356;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

Qy          1 CTTGGTCCTGATGTCTGACCATGGAGATGTGAGCCTCCCGCCCGAAGACCGGGTGAGGGC 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        107 CTTGGTCCTGATGTCTGACCATGGAGATGTGAGCCTCCCGCCCGAAGACCGGGTGAGGGC 166

Qy         61 TCTCTCCCAGCTGGGTAGTGCGGTAGAGGTGAATGAAGACATTCCACCCCGTCGGTACTT 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        167 TCTCTCCCAGCTGGGTAGTGCGGTAGAGGTGAATGAAGACATTCCACCCCGTCGGTACTT 226

Qy        121 CCGCTCTGGAGTTGAGATTATCCGAATGGCATCCATTTACTCTGAGGAAGGCAACATTGA 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        227 CCGCTCTGGAGTTGAGATTATCCGAATGGCATCCATTTACTCTGAGGAAGGCAACATTGA 286

Qy        181 ACATGCCTTCATCCTCTATAACAAGTATATCACGCTCTTTATTGAGAAACTACCAAAACA 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        287 ACATGCCTTCATCCTCTATAACAAGTATATCACGCTCTTTATTGAGAAACTACCAAAACA 346

Qy        241 TCGAGATTACAAATCTGCTGTCATTCCTGAAAAGAAAGACACAGTAAAGAAATTAAAGGA 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        347 TCGAGATTACAAATCTGCTGTCATTCCTGAAAAGAAAGACACAGTAAAGAAATTAAAGGA 406

Qy        301 GATTGCATTTCCCAAAGCAGAAGAGCTGAAGGCAGAGCTGTTAAAACGATATACCAAAGA 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        407 GATTGCATTTCCCAAAGCAGAAGAGCTGAAGGCAGAGCTGTTAAAACGATATACCAAAGA 466

Qy        361 ATATACAGAATATAATGAAGAAAAGAAGAAGGAAGCAGAGGAATTGGCCCGGAACATGGC 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        467 ATATACAGAATATAATGAAGAAAAGAAGAAGGAAGCAGAGGAATTGGCCCGGAACATGGC 526

Qy        421 CATCCAGCAAGAGCTGGAAAAGGAAAAACAGAGGGTAGCACAACAGAAGCAGCAGCAATT 480
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        527 CATCCAGCAAGAGCTGGAAAAGGAAAAACAGAGGGTAGCACAACAGAAGCAGCAGCAATT 586

Qy        481 GGAACAGGAACAGTTCCATGCCTTCGAGGAGATGATCCGGAACCAGGAGCTAGAAAAAGA 540
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        587 GGAACAGGAACAGTTCCATGCCTTCGAGGAGATGATCCGGAACCAGGAGCTAGAAAAAGA 646

Qy        541 GCGACTGAAAATTGTACAGGAGTTTGGGAAGGTAGACCCTGGCCTAGGTGGCCCGCTAGT 600
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        647 GCGACTGAAAATTGTACAGGAGTTTGGGAAGGTAGACCCTGGCCTAGGTGGCCCGCTAGT 706

Qy        601 GCCTGACTTGGAGAAGCCCTCCTTAGATGTGTTCCCCACCTTAACAGTCTCATCCATACA 660
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        707 GCCTGACTTGGAGAAGCCCTCCTTAGATGTGTTCCCCACCTTAACAGTCTCATCCATACA 766
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Qy        661 GCCTTCAGACTGTCACACAACTGTAAGGCCAGCTAAGCCACCTGTGGTGGACAGGTCCTT 720
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        767 GCCTTCAGACTGTCACACAACTGTAAGGCCAGCTAAGCCACCTGTGGTGGACAGGTCCTT 826

Qy        721 GAAACCTGGAGCACTGAGCAACTCAGAAAGTATTCCCACAATCGATGGATTGCGCCATGT 780
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        827 GAAACCTGGAGCACTGAGCAACTCAGAAAGTATTCCCACAATCGATGGATTGCGCCATGT 886

Qy        781 GGTGGTGCCTGGGCGGCTGTGCCCACAGTTTCTCCAGTTAGCCAGTGCCAACACTGCCCG 840
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        887 GGTGGTGCCTGGGCGGCTGTGCCCACAGTTTCTCCAGTTAGCCAGTGCCAACACTGCCCG 946

Qy        841 GGGAGTGGAGACATGTGGAATTCTCTGTGGAAAACTGATGAGGAATGAATTTACCATTAC 900
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        947 GGGAGTGGAGACATGTGGAATTCTCTGTGGAAAACTGATGAGGAATGAATTTACCATTAC
1006

Qy        901 CCATGTTCTCATCCCCAAGCAAAGTGCTGGGTCTGATTACTGCAACACAGAGAACGAAGA 960
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1007 CCATGTTCTCATCCCCAAGCAAAGTGCTGGGTCTGATTACTGCAACACAGAGAACGAAGA
1066

Qy        961 AGAACTTTTCCTCATACAGGATCAGCAGGGCCTCATCACACTGGGCTGGATTCATACTCA
1020
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1067 AGAACTTTTCCTCATACAGGATCAGCAGGGCCTCATCACACTGGGCTGGATTCATACTCA
1126

Qy       1021 CCCCACACAGACCGCGTTTCTCTCCAGTGTCGACCTACACACTCACTGCTCTTACCAGAT
1080
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1186

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1140
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1246

Qy       1141 TAAACTAACTGACCATGGACTAGAGGAGATTTCTTCCTGTCGCCAGAAAGGATTTCATCC
1200
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Qy       1201 ACACAGCAAGGATCCACCTCTGTTCTGTAGCTGCAGCCACGTGACTGTTGTGGACAGAGC
1260
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1366
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```
Qy       1261 AGTGACCATCACAGACCTTCGATGAGCGTTTGAGTCCAACACCTTCCAAGAACAACAAAA
1320
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Qy       1321 CCATATCAGTGTACTGTAGCCCCTTAATTTAAGCTT 1356
             |||||||||||||||||||||||||||||||||||
Db       1427 CCATATCAGTGTACTGTAGCCCCTTAATTTAAGCTT 1462
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In the response filed 8/22/06 Applicants argue, *"Yu (AF052135) fails to disclose or suggest an hAMSH protein, let alone one having the amino acid sequence of SEQ ID NO: 1. In fact, Yu (AF052135) fails to disclose an amino acid sequence. Instead, Yu (AF052135) discloses a nucleic acid, and not a protein. Also, Yu (AF052135) fails to disclose the function of the protein as a signal transduction molecule for cell proliferation. In reply to these arguments, the Office maintained the rejection on the basis that the nucleic acid sequence in Yu (AF052135) encompasses the hAMSH protein of SEQ ID NO: 1 and the nucleotide sequence of SEQ ID NO: 2."* Applicants further argue, *"claim 1 is neither anticipated or rendered obvious by Yu (AF052135), because the reference fails to disclose or suggest the hAMSH protein of SEQ ID NO: 1 of claim 1. In addition, contrary to the Office's position, it is respectfully submitted that a nucleic acid sequence cannot encompass an amino acid sequence, because they are two distinct chemical entities. For this reason alone, Yu (AF052135) cannot encompass the hAMSH protein of SEQ ID NO: 1."*

Applicants' arguments have been fully considered but they are not found persuasive. The protein of SEQ ID No:1 is encoded by a polynucleotide that starts with an ATG codon, the starting A nucleotide being at position 11 of SEQ ID NO:2. The polynucleotide encoding the protein of SEQ ID No:1 ends with an TGA codon, the ending A nucleotide being at position 1285 of SEQ ID NO:2. It is well known in the art that the start codon is ATG. It is also well known in the art that TGA is a stop codon.

Therefore when a protein is translated from a polynucleotide its translation starts at methionine (codon, ATG in DNA and AUG in mRNA) and ends at TGA (TGA in DNA and UGA in mRNA). The Color Atlas of Genetics(Eberhard Passarge), page 49, shows the codon usage in mRNA . The prediction of polypeptide sequence from exons was well known in the art as disclosed by Hutchinson and Solovyev.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use the polynucleotide disclosed by Yu (see GenBank Accession No. AF052135) to determine and isolate the three fragments encoding the three possible splice variants of the protein encoded therewith using the codon identifying programs of Hutchinson and Solovyev. The ordinary artisan would have been motivated to identify the possible proteins encoded by the polynucleotide disclosed by Yu to determine the functionality encoded by the polynucleotide. A piece of DNA is useless if it cannot be associated with a function. As stated by Hutchinson (see introduction), "Improved sequence technologies and the initiatives of the Human genome project are generating large amounts of naïve DNA sequence, which has motivated the search for efficient computer algorithms to identify coding regions in genomic DNA." The ordinary artisan would have expected success at determining the polypeptides encoded by the polynucleotide disclosed by Yu (see GenBank Accession No. AF052135) and isolating the specific fragments of nucleic acid encoding said polypeptides because the level of skill is high in the Molecular Biology arts and polynucleotide sequences are routinely spliced, ligated, put into vectors, isolated and translated into to their encoded polypeptides. The techniques of transcription/

translation and polynucleotide/ protein purification are well known in the art. If more motivation is needed to look at the proteins encoded by isolated nucleic acids one has to look no further than the Human Genome Project, whose sole purpose is to provide nucleic acid sequences which will be used to determine the functionality of their encoded polypeptides. .

Applicants argue that the Yu reference does not teach the DNA encodes a functional polypeptide. In response to Applicants' assertions, the discovery of a new property of a previously known compound does not make the product patentable. The function disclosed in the present claims is inherent to the protein of the prior art. Applicant asserts that Yu fails to disclose a hAMSH protein, let alone the amino acid sequence of SEQ ID NO. 1. In response to Applicant's assertion, Yu's disclosure of the nucleic acid sequence make obvious the hAMSH protein of SEQ ID NO for reason given above. Yu's cDNA clone makes obvious the nucleotide sequence of SEQ ID NO. 2 of the instant application. Applicant also asserts that Yu do not disclose the coding region for a protein. In response to Applicant's assertion, the coding region of the protein is made obvious by the nucleotide sequence even though Yu does not mention it for reasons given above.

The preceding rejection is based on the judicial precedent following *In re Fitzgerald*, 205 USPQ 594 because the prior art is silent with regard to the properties or function of the protein

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by Tanaka et al (J. Biol. Chem. 274 (27), 19129-19135, July 2, 1999 and the GenEmbl sequence Accession U73522 of the clone contained therein)

Tanaka (U73522) discloses a polynucleotide AMSH that is 100% identical to SEQ ID NO :2 (see sequence comparison below). Tanaka also discloses the isolation of a polypeptide encoded by said polynucleotide of SEQ ID NO:2 (see Fig 3). Tanaka further discloses a vector containing hAMSH (see plasmids). Therefore Tanaka meets the limitations of claims 1, 3 and 5, absent evidence to the contrary.

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OM protein - nucleic search, using frame_plus_p2n model

Run on: August 23, 2004, 16:45:15 ; Search time 5360 Seconds
(without alignments)
3428.628 Million cell updates/sec

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Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

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ACCESSION   U73522
VERSION     U73522.1  GI:4098123
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  ORGANISM  Homo sapiens
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
            Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
REFERENCE   1  (bases 1 to 1930)
  AUTHORS   Tanaka,N., Kaneko,K., Asao,H., Kasai,H., Endo,Y., Fujita,T.,
            Takeshita,T. and Sugamura,K.
  TITLE     Possible involvement of a novel STAM-associated molecule 'AMSH' in
            intracellular signal transduction mediated by cytokines
  JOURNAL   J. Biol. Chem. 274 (27), 19129-19135 (1999)
  MEDLINE   99315854
   PUBMED   10383417
REFERENCE   2  (bases 1 to 1930)
  AUTHORS   Tanaka,N., Kaneko,K., Kasai,H., Takeshita,T. and Sugamura,K.
  TITLE     Direct Submission
  JOURNAL   Submitted (07-OCT-1996) Microbiology, Tohoku University School of
            Medicine, 2-1 Seiryo-machi Aobaku, Sendai 980-77, Japan
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QFHAFEEMIRNQELEKERLKIVQEFGKVDPGLGGPLVPDLEKPSLDVFPTLTVSSIQP

SDCHTTVRPAKPPVVDRSLKPGALSNSESIPTIDGLRHVVVPGRLCPQFLQLASANTA

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ORIGIN

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US-09-831-452-1 (1-424) x HSU73522 (1-1930)

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Qy        201 GluLysProSerLeuAspValPheProThrLeuThrValSerSerIleGlnProSerAsp 220
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Qy        221 CysHisThrThrValArgProAlaLysProProValValAspArgSerLeuLysProGly 240
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Qy        241 AlaLeuSerAsnSerGluSerIleProThrIleAspGlyLeuArgHisValValValPro 260
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Qy        421 ThrAspLeuArg 424
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OM nucleic - nucleic search, using sw model

Run on: August 23, 2004, 10:00:58 ; Search time 7421 Seconds
(without alignments)
11155.531 Million cell updates/sec

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Searched: 3470272 seqs, 21671516995 residues

Total number of hits satisfying chosen parameters: 6940544

Minimum DB seq length: 0
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Listing first 45 summaries

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Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

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DEFINITION Homo sapiens AMSH mRNA, complete cds.
ACCESSION U73522

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REFERENCE   1  (bases 1 to 1930)
  AUTHORS   Tanaka,N., Kaneko,K., Asao,H., Kasai,H., Endo,Y., Fujita,T.,
            Takeshita,T. and Sugamura,K.
  TITLE     Possible involvement of a novel STAM-associated molecule 'AMSH' in
            intracellular signal transduction mediated by cytokines
  JOURNAL   J. Biol. Chem. 274 (27), 19129-19135 (1999)
  MEDLINE   99315854
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REFERENCE   2  (bases 1 to 1930)
  AUTHORS   Tanaka,N., Kaneko,K., Kasai,H., Takeshita,T. and Sugamura,K.
  TITLE     Direct Submission
  JOURNAL   Submitted (07-OCT-1996) Microbiology, Tohoku University School of
            Medicine, 2-1 Seiryo-machi Aobaku, Sendai 980-77, Japan
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Qy        181 ACATGCCTTCATCCTCTATAACAAGTATATCACGCTCTTTATTGAGAAACTACCAAAACA 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 ACATGCCTTCATCCTCTATAACAAGTATATCACGCTCTTTATTGAGAAACTACCAAAACA 240

Qy        241 TCGAGATTACAAATCTGCTGTCATTCCTGAAAAGAAAGACACAGTAAAGAAATTAAAGGA 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 TCGAGATTACAAATCTGCTGTCATTCCTGAAAAGAAAGACACAGTAAAGAAATTAAAGGA 300

Qy        301 GATTGCATTTCCCAAAGCAGAAGAGCTGAAGGCAGAGCTGTTAAAACGATATACCAAAGA 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 GATTGCATTTCCCAAAGCAGAAGAGCTGAAGGCAGAGCTGTTAAAACGATATACCAAAGA 360

Qy        361 ATATACAGAATATAATGAAGAAAAGAAGAAGGAAGCAGAGGAATTGGCCCGGAACATGGC 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 ATATACAGAATATAATGAAGAAAAGAAGAAGGAAGCAGAGGAATTGGCCCGGAACATGGC 420

Qy        421 CATCCAGCAAGAGCTGGAAAAGGAAAAACAGAGGGTAGCACAACAGAAGCAGCAGCAATT 480
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        421 CATCCAGCAAGAGCTGGAAAAGGAAAAACAGAGGGTAGCACAACAGAAGCAGCAGCAATT 480

Qy        481 GGAACAGGAACAGTTCCATGCCTTCGAGGAGATGATCCGGAACCAGGAGCTAGAAAAAGA 540
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        481 GGAACAGGAACAGTTCCATGCCTTCGAGGAGATGATCCGGAACCAGGAGCTAGAAAAAGA 540

Qy        541 GCGACTGAAAATTGTACAGGAGTTTGGGAAGGTAGACCCTGGCCTAGGTGGCCCGCTAGT 600
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        541 GCGACTGAAAATTGTACAGGAGTTTGGGAAGGTAGACCCTGGCCTAGGTGGCCCGCTAGT 600

Qy        601 GCCTGACTTGGAGAAGCCCTCCTTAGATGTGTTCCCCACCTTAACAGTCTCATCCATACA 660
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        601 GCCTGACTTGGAGAAGCCCTCCTTAGATGTGTTCCCCACCTTAACAGTCTCATCCATACA 660

Qy        661 GCCTTCAGACTGTCACACAACTGTAAGGCCAGCTAAGCCACCTGTGGTGGACAGGTCCTT 720
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        661 GCCTTCAGACTGTCACACAACTGTAAGGCCAGCTAAGCCACCTGTGGTGGACAGGTCCTT 720

Qy        721 GAAACCTGGAGCACTGAGCAACTCAGAAAGTATTCCCACAATCGATGGATTGCGCCATGT 780
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        721 GAAACCTGGAGCACTGAGCAACTCAGAAAGTATTCCCACAATCGATGGATTGCGCCATGT 780

Qy        781 GGTGGTGCCTGGGCGGCTGTGCCCACAGTTTCTCCAGTTAGCCAGTGCCAACACTGCCCG 840
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        781 GGTGGTGCCTGGGCGGCTGTGCCCACAGTTTCTCCAGTTAGCCAGTGCCAACACTGCCCG 840
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Qy        841 GGGAGTGGAGACATGTGGAATTCTCTGTGGAAAACTGATGAGGAATGAATTTACCATTAC 900
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        841 GGGAGTGGAGACATGTGGAATTCTCTGTGGAAAACTGATGAGGAATGAATTTACCATTAC 900

Qy        901 CCATGTTCTCATCCCCAAGCAAAGTGCTGGGTCTGATTACTGCAACACAGAGAACGAAGA 960
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        901 CCATGTTCTCATCCCCAAGCAAAGTGCTGGGTCTGATTACTGCAACACAGAGAACGAAGA 960

Qy        961 AGAACTTTTCCTCATACAGGATCAGCAGGGCCTCATCACACTGGGCTGGATTCATACTCA1020
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        961 AGAACTTTTCCTCATACAGGATCAGCAGGGCCTCATCACACTGGGCTGGATTCATACTCA1020

Qy       1021 CCCCACACAGACCGCGTTTCTCTCCAGTGTCGACCTACACACTCACTGCTCTTACCAGAT1080
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1021 CCCCACACAGACCGCGTTTCTCTCCAGTGTCGACCTACACACTCACTGCTCTTACCAGAT1080

Qy       1081 GATGTTGCCAGAGTCAGTAGCCATTGTTTGCTCCCCCAAGTTCCAGGAAACTGGATTCTT1140
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1081 GATGTTGCCAGAGTCAGTAGCCATTGTTTGCTCCCCCAAGTTCCAGGAAACTGGATTCTT1140

Qy       1141 TAAACTAACTGACCATGGACTAGAGGAGATTTCTTCCTGTCGCCAGAAAGGATTTCATCC1200
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1141 TAAACTAACTGACCATGGACTAGAGGAGATTTCTTCCTGTCGCCAGAAAGGATTTCATCC1200

Qy       1201 ACACAGCAAGGATCCACCTCTGTTCTGTAGCTGCAGCCACGTGACTGTTGTGGACAGAGC1260
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1201 ACACAGCAAGGATCCACCTCTGTTCTGTAGCTGCAGCCACGTGACTGTTGTGGACAGAGC1260

Qy       1261 AGTGACCATCACAGACCTTCGATGAGCGTTTGAGTCCAACACCTTCCAAGAACAACAAAA1320
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1261 AGTGACCATCACAGACCTTCGATGAGCGTTTGAGTCCAACACCTTCCAAGAACAACAAAA1320

Qy       1321 CCATATCAGTGTACTGTAGCCCCTTAATTTAAGCTTTCTAGAAAGCTTTGGAAGTTTTTG1380
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1321 CCATATCAGTGTACTGTAGCCCCTTAATTTAAGCTTTCTAGAAAGCTTTGGAAGTTTTTG1380

Qy       1381 TAGATAGTAGAAAGGGGGGCATCACCTGAGAAAGAGCTGATTTTGTATTTCAGGTTTGAA1440
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1381 TAGATAGTAGAAAGGGGGGCATCACCTGAGAAAGAGCTGATTTTGTATTTCAGGTTTGAA1440

Qy       1441 AAGAAATAACTGAACATATTTTTTAGGCAAGTCAGAAAGAGAACATGGTCACCCAAAAGC1500
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1441 AAGAAATAACTGAACATATTTTTTAGGCAAGTCAGAAAGAGAACATGGTCACCCAAAAGC1500

Qy       1501 AACTGTAACTCAGAAATTAAGTTACTCAGAAATTAAGTAGCTCAGAAATTAAGAAAGAAT1560
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1501 AACTGTAACTCAGAAATTAAGTTACTCAGAAATTAAGTAGCTCAGAAATTAAGAAAGAAT1560

Qy       1561 GGTATAATGAACCCCCATATACCCTTCCTTCTGGATTCACCAATTGTTAACATTTTTTTC1620
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1561 GGTATAATGAACCCCCATATACCCTTCCTTCTGGATTCACCAATTGTTAACATTTTTTTC1620

Qy       1621 CTCTCAGCTATCCTTCTAATTTCTCTCTAATTTCAATTTGTTTATATTTACCTCTGGGCT1680
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Db      1621 CTCTCAGCTATCCTTCTAATTTCTCTCTAATTTCAATTTGTTTATATTTACCTCTGGGCT1680

Qy      1681 CAATAAGGGCATCTGTGCAGAAATTTGGAAGCCATTTAGAAAATCTTTTGGATTTTCCTG1740
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1681 CAATAAGGGCATCTGTGCAGAAATTTGGAAGCCATTTAGAAAATCTTTTGGATTTTCCTG1740

Qy      1741 TGGTTTATGGCAATATGAATGGAGCTTATTACTGGGGTGAGGGACAGCTTACTCCATTTG1800
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1741 TGGTTTATGGCAATATGAATGGAGCTTATTACTGGGGTGAGGGACAGCTTACTCCATTTG1800

Qy      1801 ACCAGATTGTTTGGCTAACACATCCCGAAGAATGATTTTGTCAGGAATTATTGTTATTTA1860
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1801 ACCAGATTGTTTGGCTAACACATCCCGAAGAATGATTTTGTCAGGAATTATTGTTATTTA1860

Qy      1861 ATAAATATTTCAGGATATTTTTCCTCTACAATAAAGTAACAATTAACTTA 1910
             ||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1861 ATAAATATTTCAGGATATTTTTCCTCTACAATAAAGTAACAATTAACTTA 1910
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6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 2 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim 2 is drawn to isolated human gene encoding the human protein hAMSH of claim 1.

The specification discloses the nucleic acid of SEQ ID NO:2, which consists of nucleotides 1-1910 encoding the polypeptide of SEQ ID NO:1. The disclosure SEQ ID NO:2 (cDNA) does not adequately describe the scope of the claimed genus of "gene", which encompasses polynucleotides comprising other undisclosed introns. A description of a genus of polynucleotides may be achieved by means of a recitation of

a representative number of polynucleotides, defined by the polynucleotide sequence, falling within the scope of the genus or of a recitation of structural and functional features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The specification fails to provide sufficient descriptive information, such as definitive structural and functional features of the claimed genus of polynucloeotide/nucleic acids. There is no description of the intron and exon structure of the claimed polynucleotide. Infact no intron structure is disclosed.

An adequate written description of a gene, requires a precise definition, such as by structure, formula and chemical name not a mere wish or plan for obtaining the claimed chemical invention. Accordingly, an adequate written description of the gene is more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the gene itself. Accordingly, the specification does not provide a written description of the invention of claims 2.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid or polypeptide is itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity, does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

It does not appear that Applicants were in possession of scope of the "gene" or genomic polynucleotide as claimed at the time the invention was made. There is no guidance provided to allow the skilled artisan to predict the structure of the gene other than that of SEQ ID NO:2. Even though the polynucleotide of SEQ ID NO:2 may be part of a genomic DNA segment, what besides the polynucleotide of SEQ ID NO:1 is present is not know. Due to their nature, genes are very complex structures, which are made of coding and non-coding regions (exons and introns, respectively). One skilled in the art could not predict either the number or position of introns or additional exons in

the claimed genomic polynucleotide or their nucleic acid sequences. Even assuming high skill of the artisan, one could not predict if there are additional coding regions in the claimed genus of variants and framents comprising genomic DNA, beside that which is shown in SEQ ID NO:2.

With the exception of SEQ ID NO:2, the skilled artisan cannot envision the detailed chemical structure of the gene claimed and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not achieved. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGFs were found unpatentable due to lack of written description for the broad class.

Therefore, only the isolated nucleic acid disclosed in SEQ ID NO:2 but not the full breadth of the claim meets the written description provision of 35 U.S.C. 112, first paragraph.

8. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new matter is the species of the polynucleotide which consists of the nucleotide sequence from the 11th to the 1285th nucleotide of SEQ ID No.2 . The specification does not disclose the species polynucleotide consists of the nucleotide sequence from the 11th to the 1285th nucleotide of SEQ ID No.2. Applicant is required to cancel the new matter in the reply to this Office Action.

9. The amendment filed 12/7/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: A polynucleotide encoding a human hAMSH, which is a signal trandsduction molecule for cell proliferation, wherein the polynucleotide consists of the nucleotide sequence from the 11th to the 1285th nucleotide of SEQ ID No.2. Specifically the original disclosure does not disclose the species "polynucleotide consists of the nucleotide sequence from the 11th to the 1285th nucleotide of SEQ ID No.2. "

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement

thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 3 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 3 recites a polynucleotide but do not recite that it is isolated or purified. The claim as currently recited encompasses naturally-occurring compounds. Therefore, the compounds as claimed are a product that occurs in nature and does not show the hand of man, and as such is non-statutory subject matter. It is suggested that the claims be amended to recite an "isolated and purified polynucleotide" to overcome this rejection.

11. No claims are allowed.

Advisory

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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